

1.15 CERTIFICATION OF MACHINES EMITTING RADIATION

Question: Do I own (or want to own) a non-dental, non-veterinary, or non-mammography electronic radiation producing machine?

Why do I need this approval?

All radiation machines in Maryland except mammography, dental and veterinary practices must be certified as meeting State performance standards to ensure minimal health risk and optimal safety of anyone exposed to its radiation. Affected facilities include hospitals, clinics, industries, government facilities and academic institutions that house operable x-ray machines.

What laws or regulations give MDE the legal authority to issue this approval?

FEDERAL: 21 Code of Federal Regulations, Chapter I, Subchapter J.
STATE: Environment Article, Title 8, Subtitle 3; COMAR 26.12.02.

What is the process to get this approval?

- 1) Owners (other than dentists, veterinarians, and mammographic facilities) must have a State licensed private inspector inspect the machine(s).
- 2) The inspector certifies to the Department that the machine functions properly and that necessary repairs have been made if violations have been cited.
- 3) The Department issues a certification approval letter. A state sticker with a unique machine number plus suffix, which must be affixed to the machine, will be issued to machines not previously identified.

Are there any other requirements?

PRE-APPROVAL: All applicants except dental, veterinary, and mammographic practices must hire a state licensed private inspector to examine the radiation machine and the facility, and produce certification data within the six months prior to the certification due date. If the machine is not in compliance, it must be repaired and then reevaluated by a state licensed inspector. An application must be submitted at least 45 days before the certification due date.

POST-APPROVAL: Radiation machines must undergo preventive maintenance according to manufacturer specifications including frequency of maintenance to ensure optimum operating level. The registrant is responsible for ensuring that the preventive maintenance reports generated by the registered service provider are submitted to the Department.

Any change in location of a radiation machine, even a move from one room to another, requires a State certification inspection by a State licensed private inspector.

How long should I expect it to take to get this approval once I submit a complete application?

Up to 6 months

The certification processing time may be significantly reduced if the applicant contacts the Department well before the certification due date. To ensure that the inspection will be completed in time and that approval is issued prior to certification expiration, forward the necessary paperwork to the Radiological Health Program at least 45 days before the due date.

Once I get this approval, how long will it last?

Must be renewed every one, two or three years depending on the equipment.

How much will this approval cost?

Type of Equipment	Annual installments of a biennial fee:*
Accelerators (a special high powered radiation machine)	\$871
Radiation machines used in general medical and hospitals	\$219
Machines used for research, other medical or industrial purposes	\$219
*Effective January 1, 2015	

The fee must be paid before the machine can be certified.

Do I need to know any additional information? Fees are based on the number of operational tubes at a facility and must be paid before the registration process is complete. A payment transmittal form will be provided.

Who do I contact with additional questions?

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Related link:

http://staging.mde.state.md.us/programs/Air/RadiologicalHealth/XRayApplicationFormsandGuidance/Pages/Programs/AirPrograms/radiological_health/xray_applications/index.aspx